UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

FEBRUARY 4, 2022

UNITED STATES OF AMERICA

v. **INDICTMENT NO. 2:19-cr-00202-SDM**
Filed on September 12, 2019

THOMAS ROMANO

DISCLOSURE OF DR. JAMES PATRICK MURPHY AS EXPERT WITNESS

OVERVIEW

I was asked to write a report regarding the prescribing practices of Dr. Thomas J. Romano (Defendant) in relation to INDICTMENT NO. 2:19-CR-00202-sdm. My opinion is that Dr. Romano's prescribing practices in each case mentioned in the indictment was for a legitimate medical purpose and in the usual course of professional practice.

RELEVANT EXPERIENCE

I attended medical school at the University of Louisville School of Medicine, followed by a psychiatry internship at the Naval Medical Center in San Diego. Next, I attended training as a Naval Flight Surgeon at the Naval Aerospace Medical Institute in Pensacola, Florida. I served on active duty as a Navy flight surgeon from 1987 – 1989. Upon completing my tour of active duty in the United States Navy, I attended anesthesiology residency training at the University of Louisville from 1989 – 1992. Later, I attended subspecialty fellowship training in pain management at the Mayo Clinic from 1997 – 1998, where I also served as an Associate

Consultant and Instructor of Anesthesiology for the Mayo Medical School. After my pain management fellowship, I entered private practice and started the Murphy Pain Center where, for over 22 years, I have treated and continue to treat patients with chronic pain, utilizing multiple modalities including controlled substances and interventional pain treatment procedures. Also, I actively practice addiction medicine and treat patients with substance use disorders. I am certified by three separate and distinct American Board of Medical Specialties boards in three specialties: Anesthesiology, Pain Medicine, and Addiction Medicine. I have a Master of Medical Management business degree from the University of Southern California. Since 2004, I have served the University of Louisville School of Medicine as a gratis faculty member in the Department of Anesthesiology. In 2021, I was awarded the designation of Distinguished Fellow by the American Society of Addiction Medicine. I serve on the American Medical Association's Substance Use and Pain Care Task Force. I am the President of the Kentucky Society of Addiction Medicine and serve on the board of directors of the Kentucky Harm Reduction Coalition. I have provided consultation on various projects related to pain management and addiction to the Kentucky Board of Medical Licensure as well as the Indiana Professional Licensing Agency.

My opinions are based on my knowledge of this case, my experience as an anesthesiologist, addiction medicine specialist, and pain management specialist. I have personally cared for patients suffering with medical problems similar to the patients named in the indictment. My opinions are to a reasonable degree of medical certainty. Should additional information become available, I reserve the right to change or amend these opinions.

MATERIALS REVIEWED

I have reviewed materials provided to the Defendant through discovery, which include medical files on seven patients with initials M.C., M.M., T.M., D.N., J.S., J.T., and P.T.

Materials reviewed also included:

1. Fourteen additional patient records, provide to me by counsel
2. Correspondences from the State Medical Board of Ohio
3. State of Ohio Board of Pharmacy Reports of Investigation
4. Department of Justice, Report of Investigation, Interview of Dr. Benedict Belcik, D.O.
5. Memorandum of Interview, Bureau of Workers' Compensation, June 3, 2019
6. Report of Interview, Office of Inspector General
7. Reports of Conversation, Office of Inspector General
8. Expert Review by Dr. Timothy Munzing, 8/13/2019
9. Various prescription drug monitoring reports and summaries
10. Ohio Medical Board Complaint, dated 3/18/2019

STANDARD OF REVIEW

As this is a criminal case, as opposed to a civil proceeding or medical board issue, it is imperative that a medical expert reviewing Dr. Romano's case understand certain legal standards stipulated in the statues for prescribing opioids under 21 U.S.C. § 841(a)(1). These standards differ from the standards to be applied in a medical malpractice case or a medical licensing case. The legal standard under 21 U.S.C. § 841(a)(1) is that a controlled substance may only be prescribed, administered, or dispensed for a legitimate medical purpose by a physician acting in the usual course of professional practice. The 2006 DEA Practitioner's Manual has said that federal courts have long recognized that it is not possible to expand on the phrase "legitimate medical purpose in the usual course of professional practice" in a way that will provide definitive guidelines to address all the varied situations physicians may encounter. Therefore, the courts look to recognized medical experts, to clarify the meaning of "legitimate medical purpose in the usual course of professional practice." As an experienced and recognized medical expert

specializing in pain management and addiction medicine, I am fully capable of explaining for the court, the right true meaning of this crucial phrase, upon which determining criminal versus legitimate prescribing in federal cases, such as Dr. Romano's, is solely dependent.

First, regarding the phrase "legitimate medical purpose," the American Medical Association's Code of Medical Ethics is very clear: "A patient-physician relationship exists when a physician serves a patient's medical needs." Each medication mentioned in the indictment was prescribed by Dr. Romano in an effort to treat a medical condition for which the medication is commonly prescribed by physicians. Therefore, each medication mentioned in the indictment was prescribed for a legitimate medical purpose.

Secondly, the phrase "usual course of professional practice" must not be confused with "standard of care," as it has a very different meaning. "Usual course of professional practice" refers to the usual activities of a health care professional in providing care. In contrast, "standard of care," as would apply in a medical malpractice case, refers to medical care provided in a manner that physicians of similar training might have provided under similar circumstances. Rather than federal criminal courts, state medical boards, credentialing bodies, civil enforcement actions, and medical malpractice litigations are examples of venues more properly suited to adjudicate disagreements over departures of the "standard of care." In truth, neither a departure from the standard of care nor a departure from the usual course of professional practice is necessarily a criminal act. Regardless, Dr. Romano's treatment of the patients named in the indictment was in every instance consistent with the usual course of professional practice expected of a physician practicing medicine.

Medicine is a science of uncertainty and an art of probability. Medical standards and clinical guidelines are not infallible and change over time. Clinical practice guidelines continually evolve and rightly remain subject to debate among medical experts. Uncertainty in medicine is universal and judgment is often difficult. This has been known since the age of

Hippocrates and is why virtually every clinical guideline includes a disclaimer such as that found in the 2016 Guideline for Prescribing Opioids for Chronic Pain, which states: "The recommendations in the guideline are voluntary, rather than prescriptive standards."

Instead of clinging to the premise that Dr. Romano's care must rigidly adhere to a published guideline or the opinions held by another physician, a proper review of his practice in the context of federal law must focus solely, without exception, on whether the care he provided was for a legitimate medical purpose and in the usual course of professional practice.

Considering the teachings of venerable physicians throughout the ages, foundational medical ethics, and respected bodies such as the American Medical Association, the World Health Organization, and the American Academy of Pain Medicine, the usual course of professional practice for a physician can be summarized as: knowledgeable, reasoned, and intuitive clinical judgment, with beneficent intent, leading to therapeutic action to restore, preserve, or improve health. Dr. Romano's treatment of his patients in the indictment, and his prescribing of the medications noted in the counts against him, were consistent with this right and true definition of the practice of medicine. And specifically, the medications he prescribed for the patients noted in the indictment, were in each instance, prescribed for a legitimate medical purpose and in the usual course of professional practice.

CONCLUSIONS

First of all, it is indisputable that Dr. Romano is a highly credentialled, highly skilled, and highly experienced physician, medical scholar and educator. He certainly knows how to treat pain. Applying the standard outlined above, I conclude that Dr. Romano's treatment of the seven patients noted in the indictment was for a legitimate medical purpose in the usual course of professional practice in each instance. The records document a range of clinical options utilized by Dr. Romano to assess the source of his patients' pain and his attempt to offer treatment

consistent with the physician's "moral imperative" described in the AMA Code of Ethics to care for the patient and alleviate suffering.

Throughout the patient files I reviewed, including the seven patients named in the indictment, there is adequate evidence to support the devised plan of care. Dr. Romano referred his patients for laboratory studies, treatments, and consultations where necessary. His record keeping adequately served his needs. As a reviewer, the requisite information to justify treatments was discernable to me from information found throughout the patient clinical notes and additional data documented throughout the entirety of the patient records. The patient records tell the stories of legitimate therapeutic patient-provider relationships between Dr. Romano and his patients. Perhaps a detached or less experienced reviewer of these records might be inclined to be critical of a specific therapeutic decision, a certain note with documentation that is subjectively illegible, or even an omission or mistake. But in a profession like medicine, where uncertainty is the norm, tolerance of differing opinions must be respected, and condemnation of Dr. Romano's practice based upon one's personal preferences or interpretation of clinical guidelines is wrong.

Without question, Dr. Romano treated very ill patients, many of whom had been denied care from other practices in the community for various reasons. Dr. Romano offered his patients a range of therapeutic and diagnostic options, not simply opioids. Dr. Romano's patients had complex medical, psychological, and social afflictions, and the care he provided was in an attempt to alleviate their suffering. Patients came to Dr. Romano already habituated on controlled substances by previous providers. No credible medical expert can say with a broad brush that such patients, physically dependent on opioids, must be forced to taper against their will. Such a practice can be more harmful than beneficial, and can lead to catastrophic consequences for the patient. The decision to continue stable treatment, taper, or discontinue opioids or other controlled substances (e.g., benzodiazepines and carisoprodol) must be

respectful of the patient's right to autonomy and the clinical judgment of the physician in weighing the benefits against the risks for the individual patient.

I evaluated Dr. Romano's prescribing for each patient noted in the indictment. I considered every prescription in view of the totality of circumstances particular to each patient. Patients were evaluated, diagnosed, treated, and had followed up visits for reassessment. Outside consultations and tests were sought when necessary. Documentation was adequate to meet the needs of Dr. Romano. Prescriptions were dispensed with the intent to comfort and treat medical conditions for which the medication is commonly prescribed. Dr. Romano's care plans were consequent to reasoned clinical judgment, observations, and other data he used to inform his decision-making, in an effort to alleviate his patients' suffering. This is, in fact, the essence of legitimate medical purpose and the usual course of professional practice. Thus, I can conclude that for each patient named in the indictment, Dr. Romano prescribed the medications listed in the indictment for a legitimate medical purpose and in the usual course of professional practice.

Respectfully,

James Patrick Murphy, MD, MMM, DFASAM